

REMARKS

Claims 1-36 as amended are pending in the present application. In the Office Action Summary, the Examiner stated in the Disposition of Claims that Claims 2-9, 17, 18 and 34 are withdrawn from consideration. Applicants submit that Claim 34 is a generic claim and therefore should not be withdrawn. Instead, Claim 35 which belongs to unelected Species I should be withdrawn from consideration. Furthermore, claims 1, 11, 13, 14, 19, 28-31, 33 and 36 have been amended. More specifically, claims 1, 11, 13, 19 and 36 have been amended to clarify that the expandable assembly is connected to the distal end of the elongated member. Support for this amendment may be found in the published specification, *inter alia*, at paragraphs [0029] and [0040]. In addition, claims 11, 13 and 19 have been rewritten in independent form to include all recitations of the base claim and any intervening claims. Also, claim 14 has been amended to correct a typographical error by including the phrase "at a point more distal". Support for such amendment to claim 14 can be found at, *inter alia*, paragraph [0040] of the published specification. Lastly, claims 28-31 and 33 have been amended to clarify that the biologically active materials of claims 28-31 and the adhesive material of claim 33 comprise at least one of the recited biologically active material or adhesive material. No new matter has been added by these amendments.

Reconsideration and allowance of the present application in view of the remarks below are respectfully requested.

I. INFORMATION DISCLOSURE STATEMENT

A Second Information Disclosure Statement and List of References Cited by Applicant was filed September 9, 2003, a courtesy copy of which is enclosed herewith as Exhibit A. In the Office Action dated October 23, 2003, the Examiner did not initial the references on the List of References Cited by Applicant that was filed September 9, 2003. Therefore, Applicants respectfully request that these references be considered and entered into the file of the present application.

II. DRAWING OBJECTIONS

The Examiner has objected to the drawings on the ground that the drawings "fail to show a plunger in elected species II as described in the specification." It is respectfully

submitted that while a plunger is shown in the non-elected species I, Figures 1a, 1b, 1c, 1d, 1e, and 1f, a plunger is not an essential structural detail for elected species II, Figures 4a and 4b. A plunger may be present in one embodiment of species II as indicated in the specification on page 3 line 37 to page 4 line 4 but not in another embodiment as indicated in the specification on page 4 lines 5 to 22. It is respectfully requested that the Examiner's objection to the drawings be withdrawn.

III. CLAIM REJECTION UNDER 35 U.S.C. § 112

The Examiner has rejected claim 30 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner has objected to the phrase "the genetic materials" in claim 30 as lacking antecedent basis. Applicants disagree with this rejection. Claim 30 is dependent on claim 28. Claim 28 as amended recites that the biologically active material comprises at least one of cells, genetic materials and drugs. Accordingly, the term "genetic materials" in claim 30 has antecedent basis. Therefore, withdrawal of this rejection is respectfully requested.

IV. CLAIM REJECTIONS UNDER 35 U.S.C. § 103

The Examiner has rejected claims 1, 10, 15, 20-33 and 36 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,693,085 to Buirge *et al.* ("Buirge"). Applicants respectfully submit that Buirge *et al.* does not render the present invention obvious. As detailed below, the cited reference neither describes nor suggests the presently claimed subject matter.

The present invention relates to a medical device for delivery of a patch to body tissue for the administration of a biologically active material. The device comprises an elongated member having a distal end and an expandable assembly disposed at and connected to the distal end of the elongated member. The patch has two opposing surfaces, one of the opposing surface comprises an adhesive material and a biologically active material. The other opposing surface is disposed upon the expandable assembly.

Buirge teaches a vascular prostheses comprising a stent 10 and a covering sleeve 12 which comprises collagen material. Unlike the present invention, Buirge does not disclose a

medical device comprising an elongated member with an expandable assembly disposed at and connected to the distal end of the elongated member. In fact, Buirge teaches away from the present invention by disclosing that its stent 10, which the Examiner alleges is an expandable assembly, is separated from the catheter, which the Examiner alleges is the elongated member of the present invention used to implant the stent. By teaching that the stent 10 of Buirge is separated from the catheter used to implant the stent, Buirge teaches that its catheter is not connected to its stent. Thus, Buirge teaches away from an elongated member being connected to the expandable assembly as recited in the present invention.

Also, Buirge does not disclose or suggest a patch having two opposing surfaces in which one of the opposing surfaces comprises an adhesive material and a biologically active material and the other opposing surface is disposed upon at least one wire element of the expandable assembly. Assuming, for the sake of argument, that the sleeve 12 of Buirge is a patch, which in Applicants opinion it is not, Buirge does not teach or suggest that an adhesive is placed on the side of the sleeve that is opposite the side of the sleeve that contacts the stent 10. In fact, by disclosing that the sleeve is heat bonded to the stent on the side of the sleeve that contacts the stent, Buirge suggests that adhesive is placed on the side of the sleeve that contacts the stent, not the opposing side (col. 11, lines 53-65). Thus, Buirge teaches away from the invention where the adhesive is placed on the side of the patch opposite the side of the patch that contacts the expandable assembly. Therefore, Buirge does not teach or suggest the present invention. Applicants respectfully submit that rejections of Claims 1, 10, 15, 20-33 and 36 under 35 U.S.C. § 103(a) should be withdrawn.

V. ALLOWABLE SUBJECT MATTER

The Examiner stated that Claims 11-14, and 19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 11, 13, and 19 have been amended to include all of the limitations of the base claim and intervening claim. Claims 12 and 14 depend on claims 11 and 13, respectively. As such, allowance of Claims 11-14, and 19 are respectfully requested.

VI. CONCLUSION

Applicants submit that the pending claims satisfy all of the criteria for patentability and are in condition for allowance. If the Examiner has any questions, please telephone the undersigned. Please charge any required fee to Deposit Account 503013.

Respectfully submitted,

Date: March 24, 2004

Gidon D. Stern 27,469
Gidon D. Stern (Reg. No.)

Susie S. Cheng 46,616
By: Susie S. Cheng (Reg. No.)

JONES DAY
222 East 41st Street
New York, N.Y.
10017
212-790-9090

MAR 26 2004

Express Mail No EV335859314US

Date Mailed 3/24/2004

Serial No. 09/977,758

Inventor Naimark et al.

First Class Mail ☐

Filed October 15, 2001

For MEDICAL DEVICE FOR DELIVERING PATCHES

- | | |
|--|--|
| <input type="checkbox"/> Affidavit/Declaration | <input type="checkbox"/> Fee Address Indication Form |
| <input checked="" type="checkbox"/> Amendment | <input checked="" type="checkbox"/> Fee Calculation <i>3 duplicate</i> |
| <input type="checkbox"/> Application pages | <input type="checkbox"/> Issue Fee Transmittal |
| <input type="checkbox"/> Claims Drawing Sheets | <input type="checkbox"/> Letter |
| <input type="checkbox"/> Appeal, Notice of | <input type="checkbox"/> Oral Hearing Request/Confirm |
| <input type="checkbox"/> Assignment | <input checked="" type="checkbox"/> Petition to Extend Time <i>3 duplicate</i> |
| <input type="checkbox"/> Brief (in Triplicate) | <input type="checkbox"/> Petition Under 37 C.F.R. |
| <input type="checkbox"/> Declaration & Power of Attorney | <input type="checkbox"/> Power of Attorney |
| <input type="checkbox"/> Design Application | <input type="checkbox"/> Associate <input type="checkbox"/> w/Revocation |
| <input type="checkbox"/> Disclaimer | <input type="checkbox"/> Sequence Listing w/ Computer Readable and Paper Copy |
| <input type="checkbox"/> Disclaimer | <input type="checkbox"/> Small Entity Statement |
| <input type="checkbox"/> Disclosure Statement <input type="checkbox"/> Form PTO-1449 | <input type="checkbox"/> Status Letter |
| <input type="checkbox"/> w.refs. <input type="checkbox"/> w/o refs. | <input type="checkbox"/> Transmittal Letter |
| <input type="checkbox"/> Drawings, Formal | <input checked="" type="checkbox"/> Fee By Deposit Account 503013 |
| Sheets Figures | |

Other: *Exhibit A*
File no.: 10177-030-999

Sender: GDS/CJC/SSC

RECEIVED

APR 05 2004

TECHNOLOGY CENTER R3700



No Postage
stamp
necessary
if mailed
in the U.S.

BUSINESS REPLY MAIL
FIRST CLASS MAIL PERMIT NO. 1825 NEW YORK, NY

POSTAGE WILL BE PAID BY ADDRESSEE

JONES DAY
222 East 41st Street
New York, New York 10017-6702

